

*Application No. 10/642,591  
Amendment dated December 1, 2008  
Reply to Office Action of September 15, 2008*

*Docket No.: 0020-5166P  
Art Unit: 3731  
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**AMENDMENTS TO THE DRAWINGS**

Three sheets of Replacements Drawings are attached at the end of this Amendment in order to designate left-handed spiral wire 311a and right-handed spiral wire 311b in Figs. 3, 5, and 13. No new matter has been added.

**REMARKS**

Applicants thank the Examiner for the thorough consideration given the present application. Claims 1 and 3-9 are pending. Claim 2 was previously cancelled. Claim 1 is amended, and claim 9 is added. Claim 1 is independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

**Amendments to the Drawings**

Three sheets of Replacements Drawings are attached at the end of this Amendment in order to designate left-handed spiral wire 311a and right-handed spiral wire 311b in Figs. 3, 5, and 13. No new matter has been added.

**Amendments to the Specification**

Paragraph [0041] of the specification has been amended in order to provide antecedent basis for left-handed spiral wire 311a and right-handed spiral wire 311b, as illustrated in Figs. 3, 5, and 13, and set forth in independent claim 1. No new matter has been added.

**Rejection Under 35 U.S.C. § 112, first and second paragraphs**

Claims 1 and 3-8 stand rejected under 35 U.S.C. § 112, first and second paragraphs. These rejections are respectfully traversed.

The Examiner states that the original specification does not disclose “allowing the wires to move freely without being restricted by each other in their movements”, as recited in claim 1.

In order to overcome this rejection, Applicants have amended claim 1 to recite  
“said crossed wire member comprising a plurality of spirally-configured wires including right-handed spiral wires and left-handed spiral wires,  
one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft,  
while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally above the one of said either right-handed spiral wires or left-handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other, thereby forming an original configuration swollen in middle portion and tapered to the proximal and distal ends thereof under a normal condition.”

Support for this amendment can be seen in FIGS. 3-5. In addition, Applicants have amended the specification in order to provide proper antecedent basis in the specification for the claimed subject matter.

Applicants respectfully submit that the claims, as amended, are fully supported by and adequately described in the written description of the invention. Accordingly, reconsideration and withdrawal of this rejections under 35 U.S.C. 112 first and second paragraphs are respectfully requested.

**Rejections Under 35 U.S.C. § 103(a)**

Claim 1, 3, 4, 7, and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Khosravi (U.S. Patent 6,361,546) in view of Brooks et al. (U.S. Patent 6,346,116); and

Claims 5 and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Khosravi in view of Brooks et al., and further in view of Rosenbluth (WO 99/56801).

These rejections are respectfully traversed.

**Amendments to Independent Claim 1**

While not conceding the appropriateness of the Examiner's rejection, but merely to advance the prosecution of the present application, independent claim 1 has been amended herein to recite a combination of elements directed to a thrombus capture catheter, including *inter alia*

"said crossed wire member comprising a plurality of spirally-configured wires including right-handed spiral wires and left-handed spiral wires,

one of said right-handed spiral wires or left-handed spiral wires being arranged spirally around said shaft to surround the shaft,

while the other of said right-handed spiral wires or left-handed spiral wires being arranged spirally above the one of said either right-handed spiral wires or left-handed spiral wires so that said right-handed spiral wires and left-handed spiral wires to cross each other, thereby forming an original configuration swollen in middle portion and tapered to the proximal and distal ends thereof under a normal condition."

In the embodiment shown in Figs. 3 and 13, the crossed wire member (31) comprises eight spirally-configured wires (311), i.e., four left-handed spiral wires (311a) and four right-handed spiral wires (311b), which are fashioned into a spiral shape consisting of one turn. In the figures, all the right-handed spiral wires (311b) are drawn by solid black lines, while the left-handed spiral wires (311a) are drawn by broken lines cut off in the parts where the left-handed spiral wire (311a) and right-handed spiral wire (311b) cross each other. This clearly teaches that all the right-handed spiral wires (311b) are wound around a shell created by the left-handed spiral wires (311a).

Accordingly, it can be said that the left-handed spiral wires (311a) are arranged spirally around the shaft (2), while the right-handed spiral wires (311b) are arranged spirally above the left-handed spiral wires (311a). Thus, the right-handed spiral wires (311b) and the left-handed spiral wires (311a) cross each other as shown in Fig. 13, but the former merely surround the latter and are not woven into the left-handed spiral wires (311a).

It can be easily imagined that the right-handed spiral wires (311b) the left-handed spiral wires (311a) can be counterchanged with each other. Thus, it can be concluded that one group of the spirally-configured wires, i.e., either right-handed spiral wires (311b) or left-handed spiral wires (311a), are arranged spirally around the shaft (2), while the other group of spirally-configured wires are arranged spirally around the left-handed spiral wires (311a), thereby allowing left-handed spiral wires (311a) and right-handed spiral wires (311b) to cross each other, as shown in Fig. 13. Such a structure of the crossed wire member allows the left-handed spiral wires (311a) and right-handed spiral wires (311b) to expand and

contract longitudinally and radially without being restricted by each other in their movements.

The above crossed wire member may be made, for example, by a process including the steps of:

preparing left-handed spiral wires (311a) and right-handed spiral wires (311b) respectively;

arranging the left-handed spiral wires (311a) around the shaft (2) with a certain distance between them and fixing them at both ends thereof to a shaft (2) or fixed ring (34) and an inner ring (331) slidably mounted on the shaft (2) to form a spindle-shaped shell;

arranging and fixing one end of the right-handed spiral wire (311b) in the predetermined position between proximal ends of the adjoining left-handed spiral wires (311a) fixed on the shaft (2) or fixed ring (34);

allowing the right-handed spiral wires (311b) to wind around the spindle-shaped shell of the left-handed spiral wires (311a);

arranging the other end of the right-handed spiral wire (311b) in the predetermined position between the distal ends of the adjoining left-handed spiral wires (311a) and fixing them to the inner ring (331); and,

fixing an outer ring (332) on the distal ends of the spiral wires (311a, 311b).

Accordingly, the present invention allows the spirally-configured wires 311 to move freely without being restricted by each other in their movements at the time of expanding and shrinking of the thrombus capture member. The function of the above construction is promoted by another feature, i.e., the fact that the crossed wire member is fixed at the proximal end thereof to a shaft (guide wire), but is slidably mounted at the distal and thereof on the shaft. This facilitates elongation and contraction of the spirally-configured wires, i.e., expanding and shrinking of the thrombus capture member.

According to the present invention, the thrombus capture catheter enables reliably capturing of the thrombus as well as performing percutaneous transluminal angioplasty with ease without preventing the blood flow to peripheral blood vessels through a diseased site of the vessel. Because the spirally-configured wires are arranged around the shaft by surrounding it spirally, the shaft passes through the center of the thrombus capture member, thus making it possible to hold the thrombus capture member in uniform contact with the wall of the blood vessel. Further, since the spirally-configured wires are arranged around the shaft by surrounding it spirally so as to cross each other, the spirally-configured wires move freely without being restricted by each other in their movements at the time of expanding and shrinking of the thrombus capture member. This makes it possible to perform percutaneous transluminal angioplasty with ease.

As previously argued in the Amendment dated June 12, 2008, in contrast to the present invention, Khosravi merely discloses a vascular filter (10) or a thrombus capture member (14, 16) to be used in combination with a delivery device (50) including an elongate

tubular sheath (52) and an elongate bumper member (54) slidably disposed within the sheath (52).

The vascular filter (10) comprises an elongate tubular member (12), an expandable frame (14), and filter material (16) attached to the expandable frame (14) and/or the tubular member (12). The expandable frame (14) comprises a plurality of wire elements (24) and is attached at the distal ends 28 to the outer surface 18 of the tubular member, and at the proximal ends 26 to an annular collar 30 slidable on the tubular member 12.

However, the thrombus capture member (14, 16) is adapted to assume a collapsed condition (FIG. 2A) and an enlarged condition (FIG. 1), which differs from the deformation of the thrombus capture member of the present invention. This is because the crossed wire member of the present invention does not take a collapsed condition, but instead takes an elongated condition and a contracted condition.

Further, it is to be noted that the bumper member 54 of Khosravi is a independent member separated from the thrombus capture member (14, 16) and is combined only when pushing the thrombus capture member (14, 16) through the outlet 66 and into the vessel 100 (columns 5, line 48 – column 6, line 10). After locating the thrombus capture member (14, 16) in the blood vessel, the bumper member 54 is removed from the blood vessel (see FIG. 2C and 2D). Thus, the combination of the shaft 12 and member 54 differs in both construction and function from the flexible shaft of the present invention.

In addition, Khosravi teaches nothing about the construction of the crossed wire member as being spirally-configured and crossed with respect to each other.

Brooks et al. disclose a filter assembly basket 58 comprising struts 56 for supporting a filter membrane and teaches that struts 56 have a dense braid on distal portion 60 that transitions to a less dense braid on proximal portion 62 (column 4, lines 36-52). From FIG. 4, it appears that struts are spiral and crossed with one another. However, the filter assembly basket 58 is fixed to the guide wire 64 at its proximal end 66 and distal end 68, and thus the filter basket 58 is collapsed around the guide wire 65 and housed within sheath 70 as well as the filter assembly 12 shown in FIG. 2. This clearly teaches that the filter assembly of Brooks et al. differs in function and construction of the present invention.

At least for the reasons explained above, Applicants respectfully submit that the combination of elements as set forth in independent claim 1 is not disclosed or made obvious by the prior art of record, including Khosravi and Brooks et al.

Therefore, independent claim 1 is in condition for allowance.

**Dependent Claims**

Dependent claim 9 has been added.

All dependent claims are in condition for allowance due to their dependency from allowable independent claims, or due to the additional novel features set forth therein.

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Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

### CONCLUSION

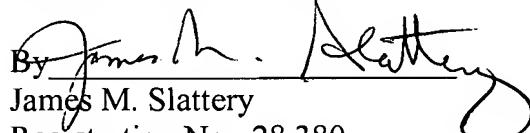
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 208-4030 (direct line).

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Dated: December 1, 2008

Respectfully submitted,

By   
James M. Slattery  
Registration No.: 28,380  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachment: Three sheets of Replacement Drawings (Figs. 3, 5, and 13).

  
JMS/CTT/ktp